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Bryan Cave LLP 1290 Avenue of the Americas New York, NY 10104			POURBOHLOUL, SARIRA CAMILLA	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/581,511

Applicant(s)

BERG-SCHULTZ, KATJA

Examiner

S. Camilla Pourbohloul

Art Unit

1765

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13 and 26-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13 and 26-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-945)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 11/22/2010
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This action is responsive to the amendment filed on November 22, 2010.

Claims 13, 26-32 are pending. Claim 13 has been amended.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 13, 26-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Sakuta et al. (US 5,254,542).

Regarding claims 13, 26-28, Sakuta et al. discloses a method of preparing an organic silicon compound having a skeleton of UV absorbing agents such as benzotriazole or benzophenone (col. 3, lines 44-50; col. 1, lines 65-67) comprising the steps of converting the UV absorbers to allyl derivatives (col. 2, lines 17-29); adding hydrosilane compounds with alkoxy group (results in an equivalent of the crosslinkable chromophore monomers of the instant invention) (col. 9, lines 21-40); and finally subjecting the reaction product to a hydrolysis reaction with an alkoxysilane such as trimethoxysilane (reads on the crosslinkable monomer of the instant invention) (col. 9, lines 60-64; col. 11, lines 13-18). The product of Sakuta's invention has UV absorbing capacity and blended in cosmetic compositions (col. 3, lines 44-52).

The recitation "for topical administration to human skin" in the instant claim has not been given patentable weight because the recitation occurs in the preamble and is of the future intended use.

Although, Sakuta does not explicitly describe its UV absorbing agent as a microencapsulated UV absorbing agent, however, in view of the fact that Sakuta teaches substantially the same chemical elements and the same chemical reactions as the instant claims, a reasonable basis exists to believe that the organic silicon compound with a chromophore skeleton (i.e. benzotriazole or benzophenone skeleton) disclosed by Sakuta possesses the same structure and serves the same function as the microcapsule of the present invention. More specifically, Sakuta teaches starting with a UV absorbing compound such as benzophenone and converting its phenol component into an allyl ether derivative (col. 5, line 58-col. 6, line 24) followed by reaction with a hydrosilane compound having a hydrolyzable halogen atom or alkoxy group (addition reaction) (equivalent of the crosslinkable chromophore compound of the instant claims) (col. 9, lines 20-53). The reaction product is then subject to hydrolysis reaction with a hydrolyzable chlorosilane, chloropolysiloxane, alkoxy silane, alkoxy polysiloxane or alkoxy polysilicate or polycondensation reaction with a non-hydrolyzable organopolysiloxane (correspond to the crosslinkable non-chromophore monomer of the instant invention) (col. 9, line 60-col. 10, line 18). The microencapsulated chromophores of the instant invention as recited in ¶ 0012 and ¶ 0016 of the instant specification comprise of polymeric matrix covalently bonded to crosslinkable chromophores. Thus the chromophore compounds are not enveloped by a shell but are embedded in a

silicone matrix containing polymeric structure. Since Sakuta is subjecting Therefore, the microcapsules of the instant invention are nothing but silicone matrix having intercalated crosslinkable chromophore molecules which are exactly the subject of Sakuta's invention. Thus the silicone-chromophore composition of Sakuta et al. would inherently be the same as the claimed encapsulated chromophore composition.

Regarding claim 29 and 30, Sakuta et al. teaches that the crosslinkable chromophore contains a silane group such as trimethoxysilane of Example 1 (col. 11, lines 14-33).

Regarding claim 32, Sakuta teaches the UV absorber makes up from 1 to 33 mol% of the total moles of the organic group (col. 4, lines 19-26).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 13, 26-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Avnir et al. (US 6,159,453).

Regarding claims 13 and 26, Avnir et al. discloses a method of preparing a sol-gel material with trapped sunscreen comprising condensation-polymerization of at least one monomer selected from metal alkoxides and from monomers of the formula $M(R)_n(P)_m$, wherein M is a metallic or semi metallic element (such as silicon, titanium, zinc, aluminum, zirconium) R is a hydrolyzable substituent (such as alkoxides,

aryloxides, carboxylic esters, acyloxy groups, diketonato groups, hydrolizable aza groups and chlorine), n is an integer from 2 to 6, P is a non polymerizable substituent (reads on the crosslinkable monomer of the instant invention) or a sunscreensing moiety or derivative (reads on the crosslinkable chromophore monomer of the instant invention) and m is an integer from 0 to 6, in the presence of at least one sunscreen ingredient, resulting in the entrapment of the sunscreen ingredients within the formed sol-gel matrix (col. 3, lines 33-46).

The recitation "for topical administration to human skin" in the instant claim has not been given patentable weight because the recitation occurs in the preamble and is of the future intended use.

Avnir et al. teaches in addition to sunscreen ingredients the sol-gel chromophore-doped composition contains other cosmetic ingredients (i.e. auxiliary agents) for coloring and opacity control (col. 3, lines 15-17; col. 3, lines 51-55).

Regarding claims 27, 28, 30, Avnir teaches using a combination of tri- and tetra-alkoxysilane monomers (col. 4, lines 48-51; col. 5, lines 44-48) in the presence of basic or acidic catalysts for entrapping sunscreen agents such as cinnamate, salicylate, and benzophenone (col. 6, lines 8-27), as well as surfactants (col. 5, lines 51-67).

Regarding claim 29, Avnir et al. teaches chromophoric monomers of the formula $M(R)_n(P)_m$, with R being a hydrolysable group such as an alkoxides group and n is an integer from 2-6 (col. 3, lines 33-46) (reads on at least two C_{1-6} alkoxy groups of the instant claim).

Regarding claim 31, Avnir et al. discloses the sol-gel matrices are particles in the range of 0.01-100 microns in diameter (col. 3, lines8-31).

Although, Avnir's sunscreen composition contains non-crosslinkable chromophores in addition to crosslinkable chromophores, it is the examiner's position that one of ordinary skill in the art would have found it obvious not to include the extra suncreening component to the sol-gel composition as long as a satisfactory suncreening effect was achieved with the crosslinkable chromophores alone.

Avnir teaches that its sol-gel sunscreen material comprises two components: one is a metal alkoxide monomer of formula $M(R)_n(P)_m$ which contains a suncreening moiety "P", and a noncrosslinked sunscreen monomer. It would be obvious to one skilled in the art to leave out the non-crosslinkable sunscreen moiety as long as there is a sunscreen component present in the sol-gel matrix in order to reduce the chances of getting free sunscreen monomers in contact with skin and thus improve the safety of the sunscreen composition.

The prior art has recognized the problem with absorption of chromophore monomers in sunscreen products and has proposed and invented a sunscreen product that isolated chemical sunscreens from the body and reduced the chances of the skin coming into contact with free chromophore (col. 1, lines 55-66). Along the same line of reasoning, it would have been obvious not to include a non-crosslinkable chromophore in the sunscreen component if there was enough of the crosslinkable chromophore attached to the metal alkoxide monomer.

Furthermore, the applicant is taking a step backward to omit part of a sunscreen which is not desired to possibly make it more cost efficient or to make it more leach proof. Elimination of an element and its function is obvious if the function of the element is not desired. See MPEP 2144.04II. Ex parte Wu , 10 USPQ 2031 (Bd. Pat. App. & Inter. 1989)

Claim Rejections - 35 USC § 103

Claims 13, 26-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spange et al. (Angew. Chem. Int. Ed. 2002, 41, 10, 1729-1732) in view of Avnir et al. (US 6,159,453).

Regarding claim 13, Spange et al. discloses a chromophoric silicate-based xerogel wherein the encapsulated components show improved retention within the microcapsule due to a new sol-gel procedure (pg. 1729, left column, second paragraph). The first step of the encapsulation procedure involves the covalent modification of a trialkoxysilane with an organic (e.g. chromophoric) group (reads on the crosslinkable chromophore monomer of the instant invention) (pg. 1729, left column, second paragraph). More specifically, a fluorine atom in a chromophoric substance such as fluorobenzophenone, a UV-A absorber (reads on the UV-A filter activity of the crosslinkable monomer of the instant invention) (pg. 1729, right column, first paragraph; Table 1) is substituted by a primary or secondary amine bonded to an alkoxy silane in tetraethoxysilane (TEOS) (e.g. aminopropyltrimethoxysilane, APS). The functionalized trialkoxysilane is subsequently converted into an organically modified silica gel (i.e. sol-

gel hybrid; page 1729, Scheme 1) by addition of tetraalkoxysilane (reads on the crosslinkable monomer of the instant invention) in the absence of a non-crosslinkable chromophore (pg. 1729, left column, third paragraph).

Although, Spange does not refer to its silicate-based xerogel as a sunscreen composition, however, due to the elements and nature of xerogel composition, the xerogel composition of Spange would be expected to possess the same suncreening abilities as that of the instant invention. Furthermore, the recitation "for topical administration to human skin" in the instant claim has not been given patentable weight because the recitation occurs in the preamble and describes a future intended use.

Although, Spange teaches a method of encapsulating chromophores with an improved sol-gel process, it fails to teach its product used in a sunscreen composition with cosmetic auxiliary agent. However, Avnir et al. teaches a method of entrapping chromophore derivatives in a sol-gel composition wherein the product is utilized as a sunscreen composition and in addition to sunscreen ingredients it contains other cosmetic ingredients for coloring and opacity control (col. 3, lines 15-17; col. 3, lines 51-55). Avnir et al. teaches that its sol-gel matrices isolate chromophores from skin, preventing their absorption through the skin and thus protect the skin. Avnir et al. teaches that the traditional method of isolating or encapsulating carcinogenic chemical sunscreens a method of entrapment of chemical compounds quite different from simple encapsulation Avnir et al. teaches that due to the carcinogenic nature of chemical sunscreens, it is essential to isolate the chemical sunscreen agents from the body while retaining the sunscreen ability to absorb light (col. 1, lines 65-col.2, lines 1-5).

Therefore, it would have been obvious to one of ordinary skill in the art to apply a UV absorbing agent as a sunscreen agent as taught by Avnir et al. to the transparent sol-gel matrix of Spange et al. in order to entrap and isolate the sunscreen agent from the body.

Avnir et al. teaches that previous attempts to entrap sunscreen ingredients in organic polymers or in plastic carriers have been unable to tightly trap dopants because small molecules are able to diffuse in and out of the polymers (col. 2, line 16-28). Recent advances in the field of sol-gel doping has opened a new wide range of applications quite different from the conventional applications of sol-gel matrix in dye laser material or non-linear optical material. Recent developments have demonstrated several technological attractive properties of sol-gel matrices such as ability to isolate a single doping molecule, ability to prevent leaching of the trapped compounds and the simplicity of the procedure (col. 2, lines 53-67 as evidenced by Avnir et al. US 5,300,564). Taking into account the newly discovered beneficial properties of sol-gel technology, it would have been obvious to one skilled in the art of sunscreen product formulation to apply a UV absorbing agent as taught by Avnir et al. to the transparent sol-gel matrix of Spange et al. in order to provide well-sequestered matrices for entrapment and isolation of dyes or other organic chemicals.

Regarding claim 26, Spange et al. discloses a sol-gel chromophore hybrid containing a chromophore with UV-A and/or UV-B filter activity such as fluorobenzophenone (page 1729, right column, first paragraph). The spacer group $(B)_b(C)_c(D)_d(E)_e$ is optional because b, c, d, and e could be 0 or 1.

Regarding claims 27, 28, Spange et al. discloses a sol-gel process resulting in a sol-gel hybrid material (equivalent of the crosslinkable chromophore with UV filter activity) (Scheme 1: page 1729, right column) is a crosslinkable monomer prepared by reacting a UV-A, UV-B, and/or UV-C chromophore such as a fluorinated benzophenone (equivalent of "P" of the general formula $M(R)_n(P)_m(Q)_q$ of the instant invention) with a aminoalkylalkoxysilane (APS) to give rise to a chromophoric xerogel such as 4-fluorobenzophenone:aminopropyltrimethoxysilane (APS) (equivalent of the chromophore monomer of Ex. 1: (triethoxysilyl)propyloxyphenyl-benzoxazole, and equivalent of the $M(R)_n(P)_m(Q)_q$ where M is a silicon element, R is hydrolysable group such as an alkoxides and Q is a non-hydrolyzable group such as an C₁-C₆ alkyl group as cited in paragraph 18-26 of the specification) (page 1730, Table 1; page 1730, right column, first paragraph).

Regarding claim 29, Spange et al. discloses a sol-gel chromophore hybrid containing a silane with at least two C₁₋₆ alkoxy groups (fluorobenzophenone:aminopropyltrimethoxysilane) (page 1730, Table 1).

Regarding claim 30, Spange et al. discloses using a crosslinkable silane monomer in the process of sol-gel chromophore hybrid production, wherein the silane monomer is tetraethoxysilane (reads on at least two C₁₋₆ alkoxy groups of the instant claim) (page 1729, left column, third paragraph).

Regarding claim 31, Spange et al. discloses that when chromophoric substances such as 4-nitroaniline derivatives are incorporated into the silicate matrix, uniformly

spherical particles with a narrow size-distribution of less than 2 μ m in diameter are formed (page 1729, right column, second paragraph; page 1731: figure 2).

Regarding claim 32, Spange discloses that the sol-gel materials prepared using this method contains up to 20% organofunctionalized silane (chromophoric silane) (pg. 1729, right column, second paragraph).

Response to Arguments

Applicant's arguments with respect to claim 13 have been considered but are moot in view of the new ground(s) of rejection.

In view of the Applicant's amendments, the rejection of claims under 35 USC 102(b) anticipated by Spange et al. has been withdrawn. Upon further consideration, a new ground(s) of rejection is made in view of a different interpretation of teachings of Sakuta et al.

Applicant has submitted Material Safety Data Sheets as Exhibit A which indicate that "tetraethyl orthosilicate" or TEOS is a hazardous substance. Applicant argues that the xerogels of Spange cannot be used as cosmetic sunscreen composition because TEOS is toxic. This assertion seems to contradict applicant's disclosure of using TEOS as a preferred crosslinkable monomer in paragraph 0075 of the instant disclosure. More specifically, applicant uses TEOS in the final stage of sol-gel microencapsulation as recited in Example 6, ¶ 0134, hence implying that TEOS is safe as a component of sunscreen product.

The recitation "for topical administration to human skin" in the amended claim 1 has not been given patentable weight because the recitation occurs in the preamble and is of the future intended use. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

In response to applicant's argument that there is no motivation to combine Avnir and Spange references, the examiner recognizes that obviousness may be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988), and *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007). In this case, the art of sol-gel matrix formation has recently provided prospects of new applications including cosmetic application. Avnir et al. teaches that previous attempts to entrap sunscreen ingredients in organic polymers or in plastic carriers have been unable to tightly trap dopants because small molecules are able to diffuse in and out of the polymers (col. 2, line 16-28). Recent developments have demonstrated several technological attractive properties of sol-gel matrices such as ability to isolate a single doping molecule, ability to prevent leaching of the trapped compounds and the simplicity

of the procedure (col. 2, lines 53-67 as evidenced by Avnir et al. US 5,300,564). Taking into account the newly discovered beneficial properties of sol-gel technology, it would have been obvious to one skilled in the art of sunscreen product formulation to apply a UV absorbing agent as taught by Avnir et al. to the transparent sol-gel matrix of Spange et al. in order to provide well-sequestered, cage-like matrices for entrapment and isolation of dyes or other organic chemicals.

Applicant alleges that the sunscreen molecules of Avnir et al. does not make covalent bonds within the sol-gel matrix. However, Avnir expressly teaches entrapment of organic compounds in inorganic sol-gel matrix by formation of covalent bonds (col. 2, lines 53-61).

In response to the examiner's position that elimination or omission of an element and its function is obvious if the element or its function is not desired, applicant has argued that in this case the issue of obviousness is not about omission of an element with undesired function (Remarks page 18, 1st paragraph) but it is about whether omission of an element results in retention of the element's function (i.e. retention of UV resistance in the absence of noncrosslinkable chromophore). Contrary to the applicant's assertion that the issue at hand is not omission of an undesired element, both the applicant and the prior art have recognized that there is an undesirable "leaching" effect of uncrosslinkable chromophore which can penetrate the skin and hence cause toxicity. Accordingly, the absence or omission of the uncrosslinkable chromophore is preferred if the product retains its sunscreen activity. Applicant claims that its inventive sunscreen composition has the same if not better sunscreensing activity than the one with

noncrosslinkable chromophores. However, to this end, the applicant has not provided any evidence or comparative examples as to how the sunscreen composition without the noncrosslinkable chromophore has the same or better suncreening abilities.

With regard to "obviousness of omission of elements with undesirable functions" the applicant argues that Avnir et al. teaches away from the present invention when it teaches the noncrosslinkable chromophore as being an "essential" part of the sunscreen composition. First, Avnir does not teach that the noncrosslinkable chromophore is "essential", and second, the applicant has not provided any evidence or comparative examples as to how the sunscreen composition without the noncrosslinkable chromophore has the same of better suncreening abilities.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Camilla Pourbohloul whose telephone number is (571)270-7744. The examiner can normally be reached on M-F 8:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 571-272-1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/James Seidleck/
Supervisory Patent Examiner, Art Unit 1765

/SCP/